

House Study Bill 173 - Introduced

HOUSE FILE _____

BY (PROPOSED COMMITTEE ON
HUMAN RESOURCES BILL BY
CHAIRPERSON FRY)

A BILL FOR

1 An Act relating to telepharmacy requirements, and including
2 effective date provisions.

3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. Section 155A.13, subsection 3, Code 2017, is
2 amended to read as follows:

3 3. a. The board may issue a special or limited-use pharmacy
4 license based upon special conditions of use imposed pursuant
5 to rules adopted by the board for cases in which the board
6 determines that certain requirements may be waived.

7 b. The board shall ~~adopt rules for the issuance of~~ issue a
8 special or limited-use pharmacy license to a telepharmacy site
9 that meets the minimum requirements established by the board by
10 rule. The rules shall address:

11 (1) Requirements for establishment and operation of a
12 telepharmacy site, including but not limited to physical
13 requirements and required policies and procedures.

14 (a) Telepharmacy site requirements for patient notification
15 shall require that a pharmacist speak with the patient over an
16 audiovisual link only when a new prescription is delivered to a
17 patient at a telepharmacy site, not when a prescription refill
18 is delivered to a patient.

19 (b) A telepharmacy site shall not be required to provide
20 services in addition to those otherwise required to be provided
21 by a licensed pharmacy.

22 (2) Requirements for being a managing pharmacy.

23 (3) Requirements governing operating agreements between
24 telepharmacy sites and managing pharmacies. The rules
25 shall require that a copy of the written contract, between
26 a telepharmacy site and a managing pharmacy that are not
27 jointly owned, shall be submitted to the board with the initial
28 application for licensure of the telepharmacy site and at any
29 time there is a substantial change in any of the terms of the
30 contract, but the written contract shall not be subject to
31 approval of the board.

32 (4) Training and experience required for certified pharmacy
33 technicians working at a telepharmacy site. The rules shall
34 require that before practicing in a telepharmacy site, a
35 certified pharmacy technician shall meet all of the following

1 requirements:

2 (a) Have successfully passed a pharmacy technician
3 certification examination accredited by the national commission
4 for certifying agencies.

5 (b) Have completed a minimum of two thousand hours of
6 practice experience as a certified pharmacy technician working
7 in a licensed pharmacy, at least one thousand hours of which
8 shall have been completed practicing in an Iowa-licensed
9 pharmacy and at least eighty hours of which shall have been
10 completed practicing in the managing pharmacy.

11 (5) Requirements for a pharmacist providing services to and
12 supervising a telepharmacy site.

13 (6) Any other health and safety concerns associated with
14 a telepharmacy site- including but not limited to all of the
15 following:

16 (a) With regard to monthly inspections, minimum on-site
17 pharmacist staffing shall be no less than eight hours per month
18 to adequately complete on-site inspections of the telepharmacy
19 site and to perform clinical services for patients.

20 (b) With regard to security, a telepharmacy site shall
21 employ methods to prevent unauthorized access to prescription
22 drugs, devices, and pharmacy and patient records. Such methods
23 may include an alarm system. Alarm systems and entry system
24 locks shall be disarmed when the telepharmacy site is staffed
25 and open to the public. Minimum security methods shall include
26 all of the following:

27 (i) The use of an electronic keypad or other electronic
28 entry system into the telepharmacy site or the pharmacy
29 department that requires and records the unique identification
30 of the individual accessing the telepharmacy site or pharmacy
31 department, including the date and time of access. Complete
32 access records shall be maintained for a minimum of two years
33 from the date of the access.

34 (ii) Secure storage such as a safe.

35 (iii) Controlled access to computer records.

1 (iv) A continuous system of video surveillance and
2 recording of the pharmacy department that includes maintenance
3 of recordings for a minimum of sixty days following the date
4 of the recording.

5 (c) (i) With regard to controlled substances, a
6 telepharmacy site that dispenses controlled substances shall
7 maintain a perpetual inventory record of the controlled
8 substances.

9 (ii) The perpetual inventory record format and other
10 requirements applicable to a pharmacy pursuant to rules adopted
11 by the board shall apply to the telepharmacy site's perpetual
12 inventory record of controlled substances with the following
13 exceptions:

14 (A) The perpetual inventory record requirement shall apply
15 to all controlled substances maintained and dispensed by the
16 telepharmacy site and shall not be limited to only schedule II
17 controlled substances.

18 (B) Audit of the perpetual inventory record shall be
19 completed and the physical and perpetual inventories shall be
20 reconciled each month, rather than no less frequently than
21 annually, as part of the inspection of the telepharmacy site.

22 (d) With regard to verification of prescriptions, a
23 pharmacist shall verify a prescription before the prescription
24 is dispensed.

25 ~~c. The board shall not issue a special or limited-use~~
26 ~~pharmacy license to a proposed telepharmacy site if a licensed~~
27 ~~pharmacy that dispenses prescription drugs to outpatients is~~
28 ~~located within ten miles by the shortest driving distance of~~
29 ~~the proposed telepharmacy site unless the~~

30 (1) A managing pharmacy shall not be required to demonstrate
31 to the board that there is a limited access to pharmacy
32 services in the community where the telepharmacy site is
33 located. However, if the distance between the proposed
34 telepharmacy site and the nearest currently licensed pharmacy
35 is less than ten miles, the board shall not issue a special or

1 limited-use pharmacy license to a proposed telepharmacy site
2 unless the managing pharmacy submits a request for a waiver of
3 the distance requirement. The distance requirement shall not
4 apply under any of the following circumstances:

5 (a) The proposed telepharmacy site is located on property
6 owned, operated, or leased by the state or unless the.

7 (b) The proposed telepharmacy site is located within a
8 hospital campus and is limited to inpatient dispensing. The
9 mileage requirement does not apply to a

10 (c) The telepharmacy site that has been was approved by the
11 board and is was operating as a telepharmacy prior to July 1,
12 2016.

13 ~~d. An applicant seeking a special or limited-use pharmacy~~
14 ~~license for a proposed telepharmacy site that does not meet the~~
15 ~~mileage requirement established in paragraph "c" and is not~~
16 ~~statutorily exempt from the mileage requirement may apply to~~
17 ~~the board for a waiver of the mileage requirement. A waiver~~
18 ~~request shall only be granted if the applicant can demonstrate~~
19 ~~to the board that the proposed telepharmacy site is located in~~
20 ~~an area where there is limited access to pharmacy services and~~
21 ~~can establish the existence of compelling circumstances that~~
22 ~~justify waiving the mileage requirement.~~

23 (2) The board's decision to grant or deny a waiver request
24 shall be a proposed decision subject to mandatory review by
25 the director of public health. The director shall review a
26 proposed decision and shall have the power to approve, modify,
27 or veto a proposed decision. The director's decision on a
28 waiver request shall be considered final agency action subject
29 to judicial review under [chapter 17A](#).

30 ~~e. The board shall issue a special or limited-use pharmacy~~
31 ~~license to a telepharmacy site that meets the minimum~~
32 ~~requirements established by the board by rule.~~

33 Sec. 2. EFFECTIVE UPON ENACTMENT. This Act, being deemed of
34 immediate importance, takes effect upon enactment.

35

EXPLANATION

1 The inclusion of this explanation does not constitute agreement with
2 the explanation's substance by the members of the general assembly.

3 This bill relates to telepharmacy requirements. The bill
4 amends provisions relating to the issuance by the board of
5 pharmacy of a special or limited-use pharmacy license to a
6 telepharmacy site. The bill provides that if a telepharmacy
7 site meets the minimum requirements established by the board
8 by rule, the telepharmacy shall be issued the license. The
9 bill eliminates the prohibition against the board issuing
10 a license to an applicant seeking a special or limited-use
11 pharmacy license for a proposed telepharmacy site if a licensed
12 pharmacy that dispenses prescription drugs to outpatients is
13 located within 10 miles by the shortest driving distance of the
14 proposed telepharmacy site, unless the proposed telepharmacy
15 meets the conditions of one of the exemptions. Instead, the
16 bill provides that a managing pharmacy shall not be required
17 to demonstrate to the board that there is a limited access
18 to pharmacy services in the community where the telepharmacy
19 site is located, but that if the distance between the proposed
20 telepharmacy site and the nearest currently licensed pharmacy
21 is less than 10 miles, the board shall not issue a special or
22 limited-use pharmacy license to a proposed telepharmacy site
23 unless the managing pharmacy submits a request for a waiver of
24 the distance requirement.

25 The bill also addresses requirements for rules to be adopted
26 by the board of pharmacy, to include specific rules that are
27 to be adopted in the areas of: requirements for establishment
28 and operation of a telepharmacy site relating to patient
29 notification and the services required to be provided by a
30 telepharmacy; the written contract between a telepharmacy
31 site and a managing pharmacy, to provide that if they are not
32 jointly owned, the contract is not subject to approval of the
33 board of pharmacy; the requirements for a certified pharmacy
34 technician practicing in a telepharmacy; and health and
35 safety concerns associated with a telepharmacy site including

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1 those relating to monthly inspections, security, controlled
2 substances, and verification of a prescription.

3 The bill takes effect upon enactment.